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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,956	05/25/2007	Chad J. Carter	59468US005	2943

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
03/30/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/596,956	CARTER ET AL.	
	Examiner	Art Unit	
	ANN LAM	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 48-66* is/are pending in the application.

4a) Of the above claim(s) *53-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 48-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/8/10, 2/9/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

It is noted that the requirement for election of species, as set forth in the Office action mailed July 15, 2009, regarding the species of the type of flow control feature, is hereby withdrawn due to a finding of allowable subject matter, as indicated further below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 7 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warthoe et al., U.S. 2004/0072208 in view of Gizeli et al., U.S. 5,478,756.

Warthoe et al. teach a sensor system for detecting a target biological analyte, the system comprising:

a surface acoustic wave sensor comprising a sensor (detection) surface;

a binding ligand (capture agent) located on the sensor surface, wherein the binding ligand is capable of selectively attaching the target biological analyte to the sensor surface;

a detection chamber located within an interior volume of a device housing, the detection chamber comprising a volume defined by the sensor surface and an opposing surface spaced apart from and facing the detection surface; and

a waste reservoir (chamber) located within the interior volume of the device housing, the waste reservoir in fluid communication with the detection chamber (see paragraphs [0017], [0018], [0022], [0023], [0028], [0062], [0068], [0074]-[0076], [0089], [0090], [0100], [0143], [0144], [0150], [0153] and [0172]).

However, Warthoe et al. do not disclose one or more flow front control features, located only on the opposing surface [i.e., opposing the detection surface, spaced apart from and facing the detection surface], as claimed by Applicant.

This however is disclosed by Gizeli et al. It is discussed by Gizeli et al. that a problem which occurs with known SAW [surface acoustic wave] sensors is that considerable penetration occurs of the acoustic wave into the environment to be sensed. If the environment is gaseous this problem is not unduly onerous. However, if (as is usually the case for analysis of biologically originating samples) the environment is liquid then the penetration of the wave into the environment causes considerable damping. This in turn reduces the sensitivity of the device. Column 1, lines 29-36.

Gizeli et al. disclose an improved form of chemical sensor of particular utility in the detection and/or determination of an analyte species in a sample which is liquid, and which overcomes or substantially mitigates the disadvantages associated with known SAW and bulk wave devices. Column 1, lines 49-55.

As part of the improved sensor, Gizeli et al. disclose that the surface of the piezoelectric support opposite the surface carrying the electrode(s) is preferably coated or intimately contacted with a material having a good impedance match with the piezoelectric material and high acoustic absorption. This is to ensure that acoustic energy propagated through the piezoelectric material is not reflected back towards the active surface of the device. Suitable materials include plastics, wax and silicone rubber. Column 2, lines 54-61.

As can be seen from FIG. 2, the chip (1) is provided on its surface bearing the electrodes (2,3) with a layer of silicon dioxide (9), and on the opposite surface with a coating of acoustically absorbing plastic tape (10). The layer of silicon dioxide (9) is approximately 3 .mu.m in thickness and covers the whole top surface of the chip (1) including the first and second electrodes (2,3). Column 4, lines 8-14.

Immobilised on the surface (within the area defined by the dashed line in FIG. 1) of the layer of silicon dioxide (9) are appropriate binding reagents for the analyte under test. Such immobilisation can be carried out by techniques which are known to those skilled in the art. Column 4, lines 15-19.

Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a material [coating] opposite the surface carrying the electrode, i.e., opposite the surface with immobilized binding reagents, a material having a good impedance match with the piezoelectric material and high acoustic absorption, such as plastic tape to ensure that acoustic energy propagated through the piezoelectric material is not reflected back towards the active surface of the device,

thus providing the benefit of increasing the sensitivity of the device. The skilled artisan would have had reasonable expectation of success because Gizeli et al. teach the same method of detection, i.e., surface acoustic wave detection, as Warthoe et al. and teach that the modifications would work to improve the detection technique.

It is noted that the materials having a good impedance match, such as plastics, wax and silicone rubber, inherently affect the flow front, and thus are equivalent to a flow front control features, and such is also supported by Applicant's disclosure that a flow front control may be a coating, such as a hydrophobic or hydrohilic coating (see e.g. paragraph 0096, 0131).

With respect to Applicant's claim 2, Warthoe et al. teach that the surface acoustic wave sensor can be a shear horizontal surface acoustic wave sensor (see paragraphs [0061]-[0062]).

With respect to Applicant's claim 7, Warthoe et al. teach that the housing further includes a capillary structure, such as a channel, located between the detection chamber and the other chambers or reservoirs, i.e., waste reservoir (see paragraphs [0144], [1050] and [0172]).

With respect to Applicant's claims 12-17, the system of Warthoe et al. includes one or more sealed modules, wherein each module comprises an exit port attached to the housing through one or more module ports that open into the interior volume of the housing, wherein at least one module contains a liquid isolated from the interior volume of the hosing, wherein said liquid can comprise a selected reagent or lysing reagent, and wherein at least two sealed modules can be connected together (i.e., first and

second chambers) with a seal isolating the modules from one another and at least one means is provided for moving material located within at least one of the modules into the interior volume of the housing (see paragraphs [0100], [0113], [0117], [0143], [0144], [0150], [0152-[0156] and [0175]-[01770.

Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warthoe et al., U.S. 2004/0072208 in view of Gizeli et al., U.S. 5,478,756, as applied to claim 1 above, and further in view of Buechler, U.S. 6,156,270.

Warthoe et al. and Gizeli et al. do not disclose an absorbent material located within the waste chamber.

However Buechler teaches that the used reagent reservoir (waste chamber) can include an absorbent material to contain the used reagent and prevent it from flowing backwards into the system (see column 20, lines 42-52; and column 21, lines 17-21.) It would have been obvious to the skilled artisan to provide an absorbent, as taught by Buechler, in the waste chamber of Warthoe et al. because Buechler teaches that this provides the benefit of preventing the used reagent from flowing backwards into the system.

With respect to claim 8, Buechler teaches the inclusion of a vent to facilitate the escape of gas and liquid filling of the reservoir (see column 8, lines 55-57.) It would have been obvious to include a vent as taught by Buechler in the Warthoe et al. device

because Buechler teaches that this provides the benefit of facilitating the escape of gas and liquid filling of the reservoir.

Claims 9 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warthoe et al., U.S. 2004/0072208 in view of Gizeli et al., U.S. 5,478,756, and further in view of Buechler, U.S. 6,156,270, and Hodges et al. (U.S. 2003/0180814).

Buechler teaches the inclusion of a vent to facilitate the escape of gas and liquid filling of the reservoir (see column 8, lines 55-57.) It would have been obvious to include a vent as taught by Buechler in the Warthoe et al. device because Buechler teaches that this provides the benefit of facilitating the escape of gas and liquid filling of the reservoir.

Warthoe et al., Gizeli et al. and Buechler, which were discussed in the 103(a) rejection above, fail to teach the inclusion of a closure element operably attached to the vent.

Hodges et al. teach an immunosensor assay device, which comprises a reaction chamber 22, a detection chamber 38, and an aperture or vent 30 that is covered by a piercing layer. The Vent allows for controlling the flow of fluid from the reaction chamber to the detection chamber, wherein when the vent, which is initially closed, is opened by means of a needle, trapped air within the system is released into the atmosphere allowing for the sample to flow from the reaction chamber and fill the detection chamber (see Figures 1 and 2; and paragraphs [0015], [0045] and [0059]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of he modified Warthoe et al. invention a closure element attached to the vent as taught by Hodges et al. because Hodges et al. teach the benefit of including a piercing layer (i.e., closure element) over a vent provided within an immunosensor device, wherein the device includes at least two chambers, in order to control the flow of fluid within the chambers of the device, wherein when te vent, which is initially closed, is opened by means of a needle, trapped air within the system is released into the atmosphere allowing for the sample to flow from one chamber and fill a second chamber.

With respect to Applicant's claim 50, Hodges et al. further teach the inclusion of a plurality of openings for the vent (see Figure 4; and paragraphs [0062], [0063] and [0071]).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Warthoe et al., U.S. 2004/0072208 in view of Gizeli et al., U.S. 5,478,756, as applied to claim 1 above, and further in view of Beebe et al., U.S. 2003/0077836.

Warthoe et al. and Gizeli et al. fail to teach that the device includes a fluid monitor operably connected to the housing.

Beebe et al. teach an apparatus for monitoring the environment within a microfluidic device, wherein the apparatus comprises a body and at least one channel for accommodating the flow of fluid therethrough. The apparatus further includes at

least one monitor structure within the channel, wherein the monitor structures allows for detecting and monitoring any change, i.e., chemical, temperature or electrical, of the fluid flowing within the channel of the device (see Figures 1 and 6; Abstract; and paragraphs [0029], [0031] and [0041]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Warthoe et al. and Gizeli et al. a fluid monitor structure as taught by Beebe et al. because Beebe et al. teach the benefit of including at least one monitor structure within a channel of a microfluidic device in order to allow for detecting and monitoring any change, i.e., chemical, temperature or electrical, of the fluid flowing within the channel of the device.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Warthoe et al., U.S. 2004/0072208 in view of Gizeli et al., U.S. 5,478,756, as applied to claim 1 above, and further in view of Ohman et al., U.S. 2005/0042766.

Warthoe et al. and Gizeli et al. fail to teach the inclusion of a magnetic field generator capable of providing a magnetic field proximate the detection surface.

Ohman et al. teach a microfluidic system comprising a substrate and at least one flow path, wherein a sample fluid is applied to the substrate and flows along the at least one flow path. The system can further include a magnet arranged in or around the flow path(s) in order to trap and retain magnetic particles or substances at desired locations in the flow path. In addition, the magnetic particles can be coated with substances

having a biological affinity for a particular target analyte (see Abstract; and paragraph [0069]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the detection surface of the device of Warthoe et al. and Gizeli et al. a magnet (i.e., magnetic field generator) as taught by Ohman et al. because Ohman et al. teach the benefit of including a magnet within a microfluidic system comprising a sample flow path in order to trap and retain magnetic particles or substances at desired locations in the flow path, wherein the magnetic particles can be coated with substances having a biological affinity for a particular target analyte.

Claims 18, 19, 22 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warthoe et al., U.S. 2004/0072208 in view of Gizeli et al., U.S. 5,478,756, as applied to claim 1 above, and further in view of Lu et al. U.S. 7,312,071.

Warthoe et al. and Gizeli et al. fail to disclose an exit seal closing the exit port of the module; a plunger located within the module, wherein the plunger is movable from a locaded position in which the plunger is distal from the exit port to an unloaded position in which the plunger is proximate the exit port; wherein movement of the plunger towards the exit port opens the exit seal such that material from the at least one module exits through the exit port into the interior volume of the housing (as recited in Applicant's claims 18, 22, 51 and 52).

However, Lu et al. discloses test cartridges for liquid or gas sample collection which further comprise a plunging means for piercing or breaking a seal of the medium reservoir (FIG. 6). The component has a knife or pointed edge that, when it contacts the medium reservoir seal with sufficient force, pierces or breaks the seal and releases the growth medium. Thus, when the plunger means is depressed, the growth medium is released from the medium reservoir. Depressing the plunger means also and simultaneously engages a seal between the medium reservoir and the semipermeable membrane. In some embodiments, this seal can be hermetic. By the action of the plunger means, the growth medium present in the reservoir is forced through the membrane in a direction opposite of the flow of the fluid sample. This has the effect of backwashing any microorganisms that can be retained on side of the semipermeable membrane opposite the medium reservoir and suspending the microorganisms in the growth medium. Column 9, line 54 to column 10, line 3.

The test cartridge also contains a sample chamber that receives the growth medium from the filter. In a preferred embodiment, microorganisms captured by the membrane are able to grow in the medium, metabolize and produce specific analytes. The movement of the growth medium into the chamber can be generated by pressure, vacuum, electrokinetics, capillary action, gravity, or a combination thereof. A breakable seal is interposed between the sample chamber and a test chamber, the latter containing a means for the detection of the target organism. Movement of fluid from the sample chamber to the test chamber following breakage of the seal between the chambers can be generated by gravity, vacuum, capillary action or other means.

Column 10, lines 4-16.

It would have been obvious to the skilled artisan to modify the Warthoe et al. invention to include a plunging means for piercing a seal of a reagent reservoir, as taught by Lu et al., in the Warthoe et al. invention because Lu et al. teach that this is a means to maintain a hermetic seal for subsequent release of the reagent in the reservoir as desired.

As to claim 19, Lu et al. teach that the movement can be generated by pressure or vacuum (column 10, lines 4-16). It is predictable that providing an actuator operably coupled to the plunger would facilitate the movement by pressure or vacuum, and such is well understood in the art. As such, providing such an actuator requires only routine skill in the art.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warthoe et al., U.S. 2004/0072208 in view of Gizeli et al., U.S. 5,478,756, and Lu et al. U.S. 7,312,071, as applied to claims 18 and 19 above, and further in view of Vedadi et al., U.S. 20030170810.

The Warthoe et al., Gizeli and Lu et al. references which were discussed in the 103(a) rejection directly above, fail to teach that the device includes a fluid monitor operably connected to the housing (claim 20), or a controller operably connected to the actuator and the fluid monitor, wherein the controller is capable of operating the actuator based on a signal from the fluid monitor (claim 21).

However, Vedadi et al. disclose that valves can be configured by corresponding controllers under the control of the control process of a software application program to selectively transfer the desired reagents or solutions into a biochemical subsystem. Pressure transducers/sensors monitor fluid and/or gas pressure levels to ensure the proper operation of the biochemical subsystem. Paragraph 0129

Thus pressure sensors to monitor fluid and controllers to ensure the proper operation of a biochemical subsystem is known in the art, as shown by Vedadi et al., and providing them in the Warthoe et al. invention would have been obvious to the skilled artisan, as it is known to provide the benefit of ensuring proper operation of a biochemical subsystem. The skilled artisan would have appreciated providing the same benefits to the Warthoe et al. invention.

Allowable Subject Matter

Claims 3-5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection.

It is noted that claim 52 was previously indicated as allowable, but upon review, the above rejection was found to be appropriate.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 6,752,963, 7,238,324, and 20070048796.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Thurs. 9-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Y. Lam/
Primary Examiner, Art Unit 1641